# Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: The HEALTHY Study Group. A school-based intervention for diabetes risk reduction. N Engl J Med 2010;363:443-53. DOI: 10.1056/NEJMoa1001933.

# ONLINE APPENDIX

## OUTCOME ASSESSMENT

### Weight and Height

Weight was measured with a digital electronic scale (SECA Alpha 882). Children were weighed without shoes and wore indoor clothing. Height was measured using a stadiometer (Perspective Enterprises, PE AIM-101). Hair styles extending above the head were measured and the height of the hairstyle (e.g., a braid) was subtracted to obtain a corrected height. Weight was measured until two assessments were ± 0.2 kg and height was measured until 2 assessments were ± 1 cm. The averages of each of the two measures were used. Height and weight were used to calculate body mass index (BMI) in $kg/m^2$, BMI z-score and BMI percentile adjusted for gender and age. At the end of $8^{th}$ grade, quality control measures were implemented. Every tenth student was remeasured by an on-site expert. The correlation between the two measurements (n= 513) was 0.999 for weight (mean difference=0.0, SD=0.4) and 0.999 for height (mean difference=0.1, SD=0.4). Immediately after measurement, values were checked by an independent on-site expert against a projected minimum and maximum range of values based on the student's base-line data and expected growth rates. If the measurement fell outside the range, the student was re-measured by the on-site expert. The correlation between the two measurements (n = 671) was 0.999 for weight (mean difference=0.0, SD=0.3) and 0.999 for height (mean difference=0.1, SD=0.4). Waist circumference was measured with a tape twice on bare skin just above the iliac crest until 2 measures were $\pm$ 1 cm. The average of the two measures was used.

## Assessment of Non-consented Children

One of the school eligibility criteria was:, "school authorities permit grade-wide collection of height, weight, gender, age, and race/ethnicity at baseline (1st semester of 6th grade)." The reason for this statement was to compare those children who participated with those who did not. The grade-wide data collection was totally anonymous and therefore did not require consent or assent. In addition to the variables mentioned above, we checked whether the student had provided consent/assent to participate in the HEALTHY health screening or not. We had no other identifying information. The participating students were re-measured during health screening for collection of baseline data.

## Glucose and Insulin

Blood samples were drawn in a fasting state, processed, and shipped to a central laboratory at the University of Washington Northwest Lipid Metabolism and Diabetes Research Laboratories (Seattle, WA) for analyses of glucose and insulin.

## Parent Feedback

After each assessment, parents/guardians received a Health Profile Summary that included their child's value for BMI percentile along with the reference categories (underweight: 0-4; healthy weight: 5-84; at risk for overweight: 85-94; overweight: 95-100). Values for blood pressure, glucose and lipids were also provided along with desirable ranges based on age and gender where applicable. Parents were encouraged to discuss any out of range values with their doctor or health care provider.

**Sample of the Parent Letter**

«Date Letter»

Dear Parents:

Thank you again for allowing your child to take part in the HEALTHY study of risks for diabetes at «School Name». We have completed your child's health screening.

Below are «First_Name» «Last_Name»'s results from this screening on «Date_Screen». More information is included about the measurements. We may not have been able to get all measures on all children. If *** is displayed, it means that we do not have this measure for your child. If you have questions about these results, please write to the HEALTHY study team at the address above or call us at «Phone_No».

Sincerely,

«PI_Name»
«PI_Title»

**How to understand your child's Health Profile Summary:**

1) **Your child's height: «Height_ft» feet, «Height_In» inches**

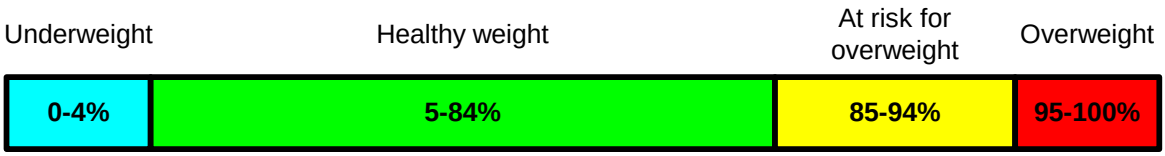
2) **Your child's weight: «Weight_lb» pounds**

3) **Your child's BMI percentile: «BMI_pct» %**

Body mass index (or BMI) looks at your child's body weight in relation to his or her height. BMI changes in children as they grow and mature. BMI percentile takes into account the differences in BMI due to height, age, and whether the child is a boy or a girl. Using BMI percentile, we can see how one child compares to others.

- A percentile less than 5% is considered underweight.
- 5%-84% is considered the healthy weight range.
- 85%-94% is considered at risk for overweight.
- 95% or greater is considered overweight.

**BMI Percentile Reference Scale:**



**4) Your child's blood pressure: «SBP»/«DBP» mm Hg**

Blood pressure in children can change as they mature. Also, noises and activity in the health screening area affect blood pressure. Don't be alarmed if your child's blood pressure is different from year to year.

- The desirable blood pressure for ages 8-10 is less than 118/77 mm Hg.
- For ages 11-14, desirable blood pressure is less than 120/80 mm Hg.
- For ages 15-17, desirable blood pressure is less than 125/80 mm Hg.

**5) Your child's fasting blood sugar: «Glu» mg/dL**

Blood sugar provides energy to muscles in the body, but a high level is a sign of diabetes. Diabetes can occur in people gradually over time and this can begin during childhood. Often this condition is first discovered by finding high blood sugar values before other symptoms occur. We have measured blood sugar under fasting conditions (your child had nothing to eat for 8 hours before the test).

- Desirable fasting blood sugar is less than 100 mg/dL.
- Any value between 100 and 125 mg/dL may indicate that your child is at risk for developing type 2 diabetes.
- A fasting blood sugar level greater than 125 mg/dL may mean that your child has diabetes.

**6) Your child's total cholesterol: «Chol» mg/dL**
**Your child's high density lipoprotein or HDL: «HDL» mg/dL**
**Your child's low density lipoprotein or LDL: «LDL» mg/dL**
**Your child's triglycerides: «Trig» mg/dL**

Total cholesterol, high density lipoprotein (or HDL), low density lipoprotein (or LDL), and triglycerides are different fats found in the blood. These values can change for many reasons. Some of those changes happen when diet changes or activity changes. Often illness and going through puberty changes these values. So just one test may not tell you all you need to know. Remember that low levels of cholesterol, LDL, and triglycerides and high levels of HDL are good and actually lower the risk of heart disease in the future.

- Desirable total cholesterol is less than 170 mg/dL.
- Desirable high density lipoprotein or HDL is greater than 35 mg/dL.
- Desirable low density lipoprotein or LDL is less than 110 mg/dL.
- Desirable triglycerides are less than 130 mg/dL.

## HEALTHY Study Health Profile Summary

**Name:** «First_Name» «Last_Name» **Measurement Date:** «Date_Screen»

| Measurements | Your Child's Values | Desirable Ranges |
|---|---|---|
| Height (feet and inches) | «Height_ft» feet, «Height_In» inches | varies |
| Weight (pounds) | «Weight_lb» pounds | varies |
| BMI percentile (%) | «BMI_pct»% | 5%-84% |
| Blood pressure (mm Hg) | «SBP»/«DBP» | age 8-10: less than 118/77<br>age 11-14: less than 120/80<br>age 15-17: less than 125/80 |
| Fasting blood sugar (mg/dL) | «Glu» | less than 100 mg/dL |
| Total cholesterol (mg/dL) | «Chol» | less than 170 mg/dL |
| High density lipoprotein or HDL (mg/dL) | «HDL» | greater than 35 mg/dL |
| Low density lipoprotein or LDL (mg/dL) | «LDL» | less than 110 mg/dL |
| Triglycerides (mg/dL) | «Trig» | less than 130 mg/dL |

We have made this summary sheet for you to share with your child's doctor or health care provider. You should talk with your child's doctor or health care provider if any test results are out of the desirable range. If your child does not have a doctor or health care provider, please call us at the phone number given above and we will help you find one.

The HEALTHY study team hopes this information is helpful in understanding your child's results. We are happy to discuss these measures with you. Call us at the number given above.

We will send these results when we do the health screening again in the 8th grade to show you how your child has changed.

**Thank you for taking part in the HEALTHY study!**

## INTERVENTION

The intervention consisted of four integrated components: nutrition; physical activity; behavioral knowledge and skills; and communications and social marketing. The rationale, techniques, and pilot testing of each component are briefly summarized below. All intervention components lasted for 5 semesters (second semester of 6$^{th}$ grade, both semesters of 7th grade, and both semesters of 8$^{th}$ grade). Each semester's activities centered on a common theme (e.g., water versus sweetened beverages, physical activity versus sedentary behavior, energy balance).

The nutrition component targeted the quantity and nutritional quality of foods and beverages served throughout the school environment (cafeteria, vending, a la carte options, snack bars, school stores, fundraisers, and classroom celebrations). It had five goals: lower the fat content of foods served; provide ≥ 2 fruit and/or vegetable servings per student at lunch and one serving at breakfast; limit dessert and snack foods to ≤ 200 kcal per item; limit beverages to water, ≤ 1% milk, and 100% fruit juice (6 oz limit, only at breakfast or as an after-school snack); and serve ≥ 2 servings of grain-based foods with ≥ 2 g of fiber per serving at lunch and 1 g of fiber per serving at breakfast.

The physical education (PE) component was designed to increase the amount of time students spent in moderate-to-vigorous physical activity (MVPA), defined as a heart rate ≥ 130 beats per minute. Intervention schools were required to schedule ≥ 225 minutes of PE over a 10-day period throughout the entire school year in order to achieve the target of ≥ 150 minutes of MVPA per 10 days. This was implemented by the school's PE teacher and a study-hired aide, using curriculum designed by study staff. The

curriculum was consistent with each state's mandated PE guidelines. Intervention schools were provided with equipment to implement the PE intervention component.

Behavioral knowledge and skills were delivered through a classroom-based program, FLASH (Fun Learning Activities for Student Health) which targeted awareness, knowledge, behavioral skills (e.g., self-monitoring, goal setting), and peer influence for behavior change. Each semester students received a series of 8-10 FLASH interactive sessions, 30 minutes each, with multiple activities per session delivered by teachers. To enhance parental support of behavior change outside the school, seven newsletters were distributed to parents featuring family vignettes that matched the semester's theme. In addition, there were two take-home vacation "break" challenges. The first was distributed during the summer between 7th and 8$^{th}$ grade, and the second was distributed before the 8$^{th}$ grade winter break. Each challenge provided parents with information and tools consistent with intervention themes. Communication strategies and social marketing integrated and supported the intervention. Campaigns included: core elements such as branding, posters, and verbal messaging (e.g., in-school announcements); student events (e.g., assemblies) and student-generated media; and distribution of premiums (e.g., t-shirts) and theme incentives (e.g., water bottles, pedometers) to extend the visibility of the intervention beyond the school environment.

**Adverse Events**

Adverse events (AE) were defined as any untoward event that occurred during the administration of or as a result of the health screening blood draw and involved local on-site medical attention. AE were recorded on a form specifying type of AE from a list of anticipated side effects from venipuncture and application of numbing cream. Variability

in rates of reported AE was attributed partly to different degrees of caution among different study personnel. Sites also experienced the 'domino effect' in which one student experienced an AE and any students who were in the vicinity tended to suffer the same experience.

Data are given in two tables. The first table shows the total number of adverse events reported during 6th grade and 8th grade health screenings by treatment group and overall. All students who were screened are included whether they were eventually determined to be ineligible or invalid and dropped from the sample, or whether they were in the cohort or new recruits at end of study.

**Total Adverse Events Reported at Health Screenings Overall and by Treatment**

| | | Baseline 6th Grade | | | End of Study 8th Grade | | |
|---|---|---|---|---|---|---|---|
| Field Center | School | # Students with AE Reported | # Students Screened* | % Students Screened with AE Reported | # Students with AE Reported | # Students Screened* | % Students Screened with AE Reported |
| CONTROL | | 75 | 3191 | 2.4% | 55 | 3168 | 1.7% |
| INTERVENTION | | 76 | 3222 | 2.4% | 50 | 3176 | 1.6% |
| OVERALL | | 151 | 6413 | 2.4% | 105 | 6344 | 1.7% |

* # students screened may include students who were later determined to be ineligible or invalid and dropped from the sample; at end of study, # students screened includes new recruits as well as cohort

The second table summarizes the specific side effects or types of adverse events overall in (a) 6th grade and (b) 8th grade. Students could experience more than one side effect in a single event. Specific comments for 'other' are listed under the table. Breakdown by treatment group is not indicated but is available.

| Distribution of Type of AE Reported at Baseline and End of Study Health Screening | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Change in skin color** | **Swelling, itching, rash** | **Bruise, hematoma** | **Dizzy** | **Fainting, LoC** | **Upset stomach, vomiting, nausea** | **Other** |
| **BASELINE** | 25 | 6 | 13 | 72 | 22 | 49 | 19* |
| **END OF STUDY** | 20 | 8 | 2 | 61 | 13 | 22 | 15** |

* 'Other' at baseline includes excessive crying, headache, arm hurts, very hot, cold and clammy, difficulty breathing, shaking, weak, throat dry, twisted ankle, pain from blood draw, numb at right shoulder and down to right leg, skin cool/sweaty and lips changed color, left eye hurt perhaps from touching numbing cream, "I don't feel so good".
** 'Other' at end of study includes shaking, weakness, headache, hot flashes, arm hurt, sweating, hyperventilating, nervous, urinated in pants, bleeding at blood draw site, "I can't feel my right arm and it feels weird but I'm ok."
Abbreviation: LoC—loss of consciousness

The HEALTHY study operationally defined a serious adverse event (SAE) as any event that occurred during the administration of or as a result of the health screening blood draw and caused bodily or psychological damage involving on-site presence of emergency medical personnel (i.e., not just the school nurse). All deaths of consented students were serious adverse events no matter when they occurred. One death was reported in a control school in the last months of the study. The 8th grade girl committed suicide on 5/28/2009; she had completed end-of-study health screening on 3/5/2009. The event was reported to NIDDK and the DSMB chair who confirmed the site determination that it was not related to the study.